complete set of the currently pending claims is also provided as Appendix B.

REMARKS

Status of the Claims.

Claims 1-4, 7-8, 10-107 are pending with entry of this amendment. Claims 5-6, 9, 99, and 100 have been cancelled without prejudice to subsequent renewal or filing in a continuation or divisional application. Claims 1-4, 7-8, 10-12, 14-24, 26-28, 30-36, 44-49, 51, 53, 55, 58-59, 61-62, 65, 67-68, 70-75, 91, 93-94, 96-97, and 100-101 are amended herein. These amendments introduce no new matter. New claims 104-107 have been added herein. These new claims introduce no new matter and support for the new claims is replete throughout the specification as filed. Any amendment to any pending claims is made without prejudice and does not constitute any acquiescence or agreement with the election/restriction requirement.

Support for the amendments to the originally pending claims and support for the new claims is found generally throughout the specification as indicated in detail below. For example, support for the amendments to claim 1 is provided in the specification, including at, but not limited to, e.g., originally filed claim 6. Support for the amendments to claims 2, 11, 14, 44-48, 55, 58, 59, and 74-75 is provided in the specification, including at, but not limited to, e.g., page 23, lines 7-9. Claim 3 has been amended to be dependent upon claim 2. Claim 4 has been amended for improved clarity. Claim 7, which is dependent upon claim 1, has been amended for consistency with amended claim 1. Support for the amendment to claim 8 is provided in the specification, including at, but not limited to, e.g., original claim 7 and page 23, lines 7-9. Support for the amendment to claim 10 is provided in the specification, including at, but not limited to, e.g., page 32, lines 10-26; page 19, lines 15-29.

Claim 12 has been amended for consistent antecedent basis with amended claim 1. Claims 21-28 and 30-36 have been amended for consistency of the specified terms and improved clarity. Claims 49, 51, 53, 61, 62, 65, 67-68, 71-73, 91, 93, 94, 97, 100, and 101 have been amended to correct an inadvertent typographical error; specifically, the plural term "claims" has been replaced with the singular term "claim". Claim 96 has been amended to correct an inadvertent spelling error. Claim 70 has been amended to correct an inadvertent error in the claim dependency.

Support for new claim 104, which is dependent upon claim 1, is found throughout the specification, including at, e.g., originally filed claim 1. Support for new claim 105, which is

dependent upon claim 10, is found throughout the specification, including at age 32, lines 10-21 and page 70, line 10 to page 71, line 5. Support for new claim 106 is found throughout the specification, including at age 32, line 27 to page 33; page 70, line 29 to page 71, line 5. Support for new claim 107 is provided throughout the specification, including at e.g., page 30, line 1 to page 31, line 16.

Election/Restriction.

The Examiner's Restriction Requirement.

In the Office Action, the Examiner restricted originally pending claims 1-103 under 35 U.S.C. § 121, requiring Applicants to elect one of the following claim groups for prosecution in the present application:

I. Claims 1-48, 62-66, 74-79, and 93-94, drawn to an isolated or recombinant nucleic acid comprising a polynucleotide sequence that promotes expression of an operably linked transgene, a vector, and a method of production of a polypeptide from a cell culture, and a kit, classified in Class 536, subclass 23.1 or class 435, subclass 320.1 or 69.1.

II. Claims 49-50, drawn to a composition that comprising [sic] the cleavage products of recombinant nucleic acids, classified in Class 536, subclass 23.1.

III. Claims 51-52, drawn to a composition that comprising [sic] the elongation products of recombinant nucleic acids, classified in Class 536, subclass 23.1.

IV. Claims 53-56, 68, and 59, drawn to a method of producing a modified nucleic acid *in vitro*, classified in Class 435, subclass 455.

V. Claims 53-55, 57-59, drawn to a method of producing a modified nucleic acid *in vivo*, classified in Class 514, subclass 44.

VI. Claims 53, 60, 61, and 67, drawn to a method of production of a nucleic acid library, a nucleic acid library, and a population of cells comprising the library, classified in Class 435, subclass 91.9.

VII. Claims 68-74, 82, and 84-92, drawn to a pharmaceutical composition comprising nucleic acid or a vector, and a method

of production of a polypeptide from a cell *in vivo*, classified in Class 514, subclass 44.

VIII. Claims 74, 82, and 83, drawn to a method of production of polypeptide from a transgenic animal, classified in Class 800, subclass 4.

IX. Claims 74, 82, and 83, drawn to a method of production of a polypeptide from a cell ex vivo, classified in Class 424, subclass 93.21.

X. Claims 95-97, drawn to a database comprising one or more character strings corresponding to a polynucleotide sequence selected from SEQ ID NO:1-18, classified in Class 360, subclass 135.

XI. Claims 98-103, drawn to a method for manipulating a sequence record in a computer system, classified in Class 702, subclass 20.

Office Action, pages 2-3.

Furthermore, the Examiner takes the position that a single nucleotide sequence or amino acid sequence must be elected for an elected Claim Group drawn to a nucleotide sequence or amino acid sequence, respectively. Office Action, pages 5-6.

Applicants' Traversal of the Restriction Requirement.

This restriction requirement is respectfully traversed on at least three grounds. First, the restriction requirement restricts subject matter ***within*** claims, in effect, requiring that single claims (*e.g.*, claims 53-55, 58-59, 74, and 82) be divided up and presented in several applications (*see, e.g.*, Claim Groups I, II, III). This flatly contravenes accepted law. As stated by the CCPA:

> As a general proposition, an applicant has a right to have ***each claim*** examined on the merits.
>
> * * *
>
> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

* * *

> It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to ***restrict* an *application*** to one of several claimed inventions . . . It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to ***reject*** a particular ***claim*** on that same basis.

* * *

> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber, Soder and Boksay, 198 USPQ 328, 331-332 (CCPA 1978) (emphasis in original and emphasis added) [hereinafter referred to as "*In re Weber*"]. *See also In re Haas*, 179 USPQ 623, 624-625 (CCPA 1973) (hereinafter referred to as *In re Haas I*); *In re Haas*, 198 USPQ 328, 334-337 (CCPA 1978) (hereinafter referred to as *In re Haas II*). Thus, the CCPA ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See In re Weber, In re Haas I,* and *In re Haas II.* Indeed, the CCPA unequivocally stated that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

> So the discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim--no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber, 198 USPQ at 334.

As the case law clearly demonstrates, restriction within a single claim is legally improper. An inventor has clear constitutional and statutory rights to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are satisfied. *See, e.g.,* MPEP § 803.02; *In re Wolfrum* 179 USPQ 620 (CCPA 1973); *In re Kuehl* 177 U.S.P.Q. 250 (CCPA 1973).

The present restriction requirement is wholly improper, since it restricts within a number of single claims. For example, claim 74 is restricted among Claim Groups I, VII, VIII, and IX. Claim 53 is restricted among Claim Groups IV, V, and VI. Claims 54-55 and 58-59 are restricted among Claim Groups IV and V. Claim 82 is restricted among Claim Groups VII and IX. The present restriction requirement precludes Applicants from pursuing the original form of these

claims and would force Applicants to file multiple divisional applications that may not capture the intended scope of the invention. Even if Applicants were to file multiple divisional applications to obtain coverage for the claims in each group set forth in the restriction requirement, Applicants would not have the opportunity to have their broader claims examined. In effect, the restriction requirement is reading into Applicants' independent claims limitations that are not present in the claims as filed. If the instant restriction requirement is allowed to stand, Applicants will never be accorded "the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ at 331.

Applicants note that the CCPA has explicitly held that review of the improper restriction of a single claim is within the jurisdiction of the Board of Patent Appeals and Interferences and the federal courts. This is in contrast to the review of ordinary restriction requirements, which are not generally subject to appellate review. *See In re* Haas I, *supra*. Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the decision is appealable. Accordingly, Applicants expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event that the restriction requirement is made final.

Second, Applicants respectfully traverse the restriction requirement because the Examiner has not established a *prima facie* case it would pose a serious burden to examine all of the pending claims such that restriction of the claims into the eleven Claim Groups is necessary. A serious burden may be *prima facie* established by presenting an appropriate and sufficient explanation of separate classification of the inventions, separate status in the art of the inventions when classifiable together, or a different field of search for one of the distinct subjects. MPEP § 803.01. If it is clear that if a search and examination of the entire application can be made without serious burden, the Examiner must examine the application on the merits, even though the application may be deemed to include claims to independent or distinct inventions. MPEP § 803.01.

Applicants note that the claims of Groups I, II, and III have been classified in the same class -- Class 536. The claims of Groups IV and VI have also been classified in the same class -- Class 435. Furthermore, the claims of Groups V and VII have been classified in Class 514. Applicants respectfully submit that the Examiner has not established by sufficient evidence or explanation that it would constitute a serious or undue burden to conduct a search and examination of all of the pending claims based upon these classifications. At the very least, Applicants

respectfully submit that it has not been sufficiently demonstrated that it would constitute an undue burden to search and examine the claims of Groups I, II, and III, since these claims have the same classification. Similarly, it has not been shown that it would pose a serious burden to search and examine the claims of Groups IV and VI, since the claims of these groups have the same classification. Nor has it been sufficiently shown that it would pose a serious burden to search and examine the claims of Groups V and VII, as these claims have been similarly classified. Applicants respectfully submit that a search and examination of the claims of these respective groups can be conducted without serious burden on the Examiner.

Third, Applicants respectfully traverse the restriction requirement because the Examiner has additionally required a further sequence restriction for each Claim Group to only one sequence. Citing MPEP § 803.04, the Examiner states that for an elected Group drawn to amino acid sequences, the Applicants must elect a single amino acid sequence, and for an elected Group drawn to nucleotide sequences, Applicants must elect a single nucleic acid sequence. Office Action, page 5. The Examiner further states that "[it] is noted that the multitude of sequence submissions for examination has resulted in undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement." Office Action, pages 5-6. In support of this statement, the Examiner presents a paragraph allegedly taken verbatim from MPEP § 803.04 which includes the following two sentences: "Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie [sic] election requirement." Office Action, page 6. Applicants are unable to locate these two specific sentences or a provision that only one sequence is to be examined in § 803.04 of the current edition of the MPEP (8th ed. August 2001). Nor were Applicants are to locate this single sequence election restriction requirement on the USPTO's website or in the current edition of the MPEP posted on the USPTO's website, which is also the 8th edition, dated August 2001.

Applicants respectfully submit that this single sequence election restriction requirement is improper, as the MPEP specifically provides that determined that ***ten nucleic acid sequences constitute a reasonable number for examination purposes.*** Section 803.04 of the MPEP (8th ed. August 2001) expressly states:

> Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements

> of 37 CFR 1.141 *et seq.* and ***permit a reasonable number of such nucleotide sequences to be claimed in a single application. It has been determined that normally ten sequences constitute a reasonable number for examination purposes.*** Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably distinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

MPEP § 803.04 (emphasis added).

Applicants respectfully traverse the sequence election restriction requirement in view of the express guidelines set forth by the Commissioner and outlined in the MPEP. Moreover, Applicants respectfully traverse this sequence election requirement because it requires restriction between a number of single claims, which is legally improper. The present application identifies 18 specific nucleic acid sequences set forth in SEQ ID NOS:1-18, respectively. Applicants believe that all 18 nucleic acid sequences constitute a reasonable number of sequences for examination purposes and their examination together would not pose an under burden on the Examiner. At the very least, based on the guidelines set forth by the Commissioner and the MPEP, ***at least 10 nucleic acid sequences should be examined in the application without restriction.***

Finally, the Examiner has included Claims 91-92 in Claim Group VII, which the Examiner states is drawn to a pharmaceutical composition comprising nucleic acid or a vector, and a method of production of a polypeptide from a cell *in vivo*. Claim 91 is directed to a nucleic acid of claim 1, 10 or 12 for use in producing *an immunogenic effect, a prophylactic effect, or a therapeutic effect in a subject.* Claim 92, which is dependent upon claim 91, further specifies that the subject is a human. Applicants respectfully submit that the explanation for the restriction of claims 91-92 in Group VII is unclear and respectfully request clarification from the Examiner on this matter. Applicants note that neither claim 91 nor claim 92 includes the limitations stated by the Examiner as pertaining to claims of Group VII (e.g., a pharmaceutical composition comprising nucleic acid or a vector, and a method of production of a polypeptide from a cell *in vivo*), and thus it would be improper to read such limitations into claim 91 or 92 during examination.

For at least the foregoing reasons, Applicants respectfully submit that both aspects of the restriction requirement are improper and request that each aspect of the restriction requirement be withdrawn.

Applicants' Election/Proposal In the Event the Restriction Requirement is Maintained.

1. Claim Group Election Requirement

In the event that the restriction requirement of the claims into the recited Claim Groups is maintained, Applicants provisionally elect Claim Group I with traverse. Applicants expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event the restriction requirement is made final.

2. Sequence Election Requirement

In one aspect, the present invention provides novel chimeric promoter nucleic acid sequences derived by recombination (e.g., "shuffling") of four known wild-type parental mammalian CMV promoter sequences and selective screening of the resulting library of chimeric nucleic acid sequences for those have promoter activities. Specifically, CMV promoter sequences of two human strains (human AD169 and human Towne) and two monkey strains (Rhesus and Vervet monkeys) were recombined. In one aspect, chimeric promoter sequences were identified that exhibited an ability to promote expression of a nucleic acid sequence that encodes a polypeptide of interest to which the chimeric promoter sequence is operably linked that was at least equal to or greater than the ability of a parental wild-type CMV promoter sequence to promote expression of the same polypeptide-encoding nucleic acid.

An alignment of 18 novel chimeric nucleotide sequences of the invention is shown in Figure 8. A number of these sequences are homologous and able to promote expression of an operably linked polypeptide-encoding nucleic acid at a level at least about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid promoted by a wild-type parental human or monkey CMV promoter sequence. For example, clones 6A8 (SEQ ID NO:8), 3C9 (SEQ ID NO:6), 9G11 (SEQ ID NO:14), 10B2 (SEQ ID NO:1), and 12H9 (SEQ ID NO:5) are closely homologous in sequence and able to promote expression of an operably linked polypeptide-encoding nucleic acid at a level about equal to or greater than the ability of a parental CMV promoter sequence to promoter expression of the same polypeptide-encoding nucleic acid (see, e.g., pages 27-33 and the Examples and figures). Each of the nucleotide sequences corresponding to clones 3C9 (SEQ ID NO:6), 9G11 (SEQ ID NO:14), 10B2 (SEQ ID NO:1), and 12H9 (SEQ ID NO:5) has about 98% sequence identity to the nucleotide sequence of clone 6A8 (SEQ ID NO:8), as can be readily determined by using the procedures set forth in the specification for calculating sequence identities.

Based upon the close homology of these five sequences (SEQ ID NO:6, SEQ ID NO:14, SEQ ID NO:1, SEQ ID NO:5, and SEQ ID NO:8), their promoter properties, and the express provision in the MPEP examination of at least 10 nucleic acid sequences is permitted, Applicants respectfully submit that it would pose no serious burden on the Examiner to search and examine at least these five sequences together in the application. In the event that a sequence election requirement is maintained, Applicants propose that at least these 5 sequences be examined together and provisionally elect these five sequence with traverse SEQ ID NOS:1, 5, 6, 8, and 14.

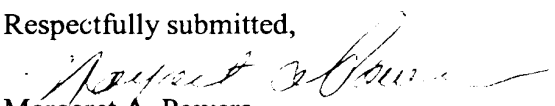
In the event the single sequence election restriction requirement is maintained and election is required of only one of the nucleic acid sequences set forth in SEQ ID NOS:1-18, Applicants provisionally elect SEQ ID NO:8 with traverse.

Applicants specifically reserve the right to pursue any non-elected claims and/or sequences in one or more continuation and/or divisional applications. Applicants expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event the single sequence election restriction requirement is made final.

Conclusion.

Withdrawal of the restriction requirement and examination of the claims is respectfully requested. **In the event the Claim Group restriction requirement and sequence election restriction requirement are maintained and election to one Claim Group and one sequence is required, Applicants respectfully request that the Examiner telephone the undersigned Applicants' attorney at (650) 298-5809 prior to examination of the claims to apprise Applicants' attorney of the final decision on this matter. Applicants would like the opportunity to amend the claims, if necessary, so that they are consistent with the Examiner's decision on the restriction requirement prior to examination.**

Respectfully submitted,



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APPENDIX A

"MARKED UP" CLAIMS ILLUSTRATING THE AMENDMENTS MADE TO THE CLAIMS OF 09/886,942 WITH ENTRY OF THIS AMENDMENT

1. (Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence **[selected from the group consisting of:**

(a) a polynucleotide sequence selected from SEQ ID NO:1 to SEQ ID NO:18 or a complementary polynucleotide sequence thereof;

(b) a polynucleotide sequence] that has at least about **[97%]** 98% sequence identity to at least one polynucleotide sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18, or a complementary polynucleotide sequence thereof**[;]**.

[(c) a polynucleotide sequence that has at least about 80% sequence identity to at least one sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18, or a complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of an operably linked transgene at a level that is greater than the level of expression of the same transgene when operably linked to a human CMV promoter polynucleotide sequence; and

(d) a polynucleotide sequence comprising a fragment of (a), (b), or (c), wherein said fragment promotes expression of an operably linked transgene at a level that is greater than the level of expression of the same transgene when operably linked to a human CMV promoter polynucleotide sequence.]

2. (Amended) The nucleic acid of claim 1, **[comprising a polynucleotide sequence of (b),]** wherein said polynucleotide sequence promotes expression of **[an]** a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked **[transgene]** at a level that is about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

3. (Amended) The nucleic acid of claim 2 **[1]**, wherein the human CMV promoter polynucleotide sequence is a Towne or AD169 human CMV promoter polynucleotide sequence.

4. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises **[comprising]** a polynucleotide sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:18 or a complementary polynucleotide sequence thereof.

Please cancel claims 5 and 6 without prejudice to subsequent renewal.

7. (Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that has at least about 99% sequence identity to at least one polynucleotide sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18 or a complementary polynucleotide sequence thereof.

8. (Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that has at least about 99% **[80%]** sequence identity to at least one polynucleotide sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18, or a complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of the polypeptide-encoding nucleic acid **[an operably linked transgene]** at a level that is about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

Please cancel claim 9 without prejudice to subsequent renewal.

10. (Amended) An isolated or recombinant nucleic acid comprising a subsequence **[fragment]** of at least one polynucleotide sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:18, said subsequence comprising nucleic acid residues at positions corresponding to position 1 to about position 909 of the consensus sequence shown in Figure 8, or **[a fragment of]** a complementary polynucleotide sequence thereof**[, wherein the fragment comprises a unique subsequence]**.

11. (Amended) The nucleic acid of claim 10, wherein the subsequence **[fragment]** promotes the expression of a nucleic acid encoding a polypeptide **[transgene]** to which the subsequence **[fragment]** is operably linked.

12. (Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that hybridizes under highly stringent conditions over substantially the entire length of a the polynucleotide sequence of claim 1 **[(a), (b), (c), or (d)]**.

14. (Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that promotes the expression of the polypeptide-encoding nucleic acid **[an operably linked transgene]** at a level that differs from the expression level of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a nucleic acid sequence corresponding to a human CMV promoter polynucleotide sequence.

15. (Amended) The nucleic acid of claim 14, wherein the polypeptide-encoding nucleic acid encodes **[transgene is luciferin]** luciferase, and **[transgene]** the expression level is determined in an *in vitro* luciferase assay.

16. (Amended) The nucleic acid of claim 14, wherein the polypeptide-encoding nucleic acid encodes **[transgene is]** β-galactosidase, the polypeptide-encoding nucleic acid **[transgene]** is expressed *in vivo* **[vivo]**, and the **[transgene]** expression level is determined by measuring the serum titer of anti-β-galactosidase antibodies.

17. (Amended) The nucleic acid of claim 14, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid **[an operably linked transgene]** at a level that is higher than the highest expression level of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a **[nucleic acid sequence corresponding to a]** human CMV promoter polynucleotide sequence.

18. (Amended) The nucleic acid of claim 17, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid **[an operably linked transgene]** at a level that is 2-fold higher than the highest expression level of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a **[nucleic acid sequence corresponding to a]** human CMV promoter polynucleotide sequence.

19. (Amended) The nucleic acid of claim 14, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid **[an operably linked**

transgene] at a level that is lower than the lowest expression level of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a **[nucleic acid sequence corresponding to a]** human CMV promoter polynucleotide sequence.

20. (Amended) The nucleic acid of claim 19, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid **[an operably linked transgene]** at a level that is 2-fold lower than the lowest expression level of the polypeptide-encoding nucleic acid **[same transgene]** when the polypeptide-encoding nucleic acid is operably linked to a **[nucleic acid sequence corresponding to a]** human CMV promoter polynucleotide sequence.

21. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more **[nucleotides]** nucleotide residues in a region corresponding to about **[nucleotides]** nucleotide residue positions 830-835 or 841-844 of the consensus sequence shown in Figure 8.

22. (Amended) The nucleic acid of claim 21, wherein the nucleic acid comprises a deletion of **[nucleotides]** nucleotide residues at positions corresponding to about **[nucleotides]** nucleotide residue positions 830-835 or 841-844 of the consensus sequence.

23. (Amended) The nucleic acid of claim 22, wherein the nucleic acid comprises a deletion of the nucleotide residues **[nucleotides]** at positions corresponding to about **[nucleotides]** nucleotide residue positions 830-835 and 841-844 of the consensus sequence.

24. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises nucleotide residues of a Rhesus monkey CMV promoter polynucleotide sequence at positions corresponding to about nucleotide residue positions 817-863**[, numbered according to]** of the consensus sequence shown in Figure 8.

26. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises an insertion of a nucleotide residue, as compared to the human Towne CMV promoter sequence, after the nucleotide residue corresponding to that positioned at position 853**[, numbered according to]** of the consensus sequence shown in Figure 8.

27. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues **[nucleotides]** in a region corresponding to about **[nucleotides]** nucleic acid residue positions 684-735 of the consensus sequence shown in Figure 8.

28. (Amended) The nucleic acid of claim 27, wherein the nucleic acid comprises a deletion of **[any nucleotides]** nucleotide residues corresponding to about **[nucleotides]** nucleotide residue positions 684-735 of the consensus sequence.

30. (Amended) The nucleic acid of claim 1, wherein the nucleic acid does not comprise **[CMV promoter]** nucleic acid residues beyond about the nucleotide residue position corresponding to position 909 of the consensus sequence, numbered according to the consensus sequence shown in Figure 8.

31. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence comprising nucleic acid residues at positions corresponding to about position 1 to about **[nucleotide residue]** position 930 of the consensus sequence**[, numbered according to the consensus sequence]** shown in Figure 8.

32. (Amended) The nucleic acid of claim 31, wherein the nucleic acid does not comprise **[CMV promoter]** nucleic acid residues beyond about the nucleotide residue at the position corresponding to position 930 of the consensus sequence**[, numbered according to the consensus sequence]** shown in Figure 8.

33. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence comprising nucleic acid residues at nucleic acid residue positions corresponding to positions 1 to **[nucleotide residue]** 932 of the consensus sequence**[, numbered according to the consensus sequence]** shown in Figure 8.

34. (Amended) The nucleic acid of claim 33, wherein the nucleic acid does not comprise **[CMV]** nucleotide residues beyond the nucleotide residue corresponding to position 932 of the consensus sequence**[, numbered according to the consensus sequence]** shown in Figure 8.

35. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues **[nucleotides]** in a region corresponding to about nucleotide **[residues]** residue positions 319-512 of the consensus sequence shown in Figure 8.

36. (Amended) The nucleic acid of claim 35, wherein the nucleic acid comprises a deletion of **[nucleotides]** nucleotide residues corresponding to about nucleotide **[residues]** residue positions 319-512 of the consensus sequence.

44. (Amended) The nucleic acid of claim **[claims]** 1, 10 or 12, wherein the polynucleotide sequence is operably linked to a nucleic acid encoding a polypeptide **[transgene]** to form an expression cassette.

45. (Amended) The nucleic acid of claim 44, wherein the polypeptide-encoding nucleic acid encodes a viral polypeptide **[transgene is a viral gene]**.

46. (Amended) The nucleic acid of claim 44, wherein the polypeptide-encoding nucleic acid **[transgene]** encodes a polypeptide selected from the group consisting of an immunogen, an immunomodulatory molecule, an antigen, an adjuvant, an allergen, an antibody, a bacterial toxin, a cytokine, a cytokine receptor, and a co-stimulatory molecule.

47. (Amended) The nucleic acid of claim 46, wherein the polypeptide-encoding nucleic acid **[transgene]** encodes an antigen selected from the group consisting of a cancer antigen, a hepatitis B surface antigen, a hepatitis A antigen, and a hepatitis C antigen.

48. (Amended) The nucleic acid of claim 46, wherein the polypeptide-encoding nucleic acid **[transgene]** encodes a co-stimulatory **[molecule comprising a]** polypeptide that binds to a CD28 or CTLA-4 receptor.

49. (Amended) A composition produced by the cleaving of one or more nucleic acids of claim **[claims]** 1, 10, or 12, wherein the cleaving comprises mechanical, chemical, or enzymatic cleavage.

51. (Amended) A composition produced by a process comprising incubating one or more nucleic acids of claim **[claims]** 1, 10, or 12 in the presence of deoxyribonucleotide triphosphates and a nucleic acid polymerase.

53. (Amended) A method of producing a modified or recombinant nucleic acid comprising mutating or recombining a nucleic acid of claim **[claims]** 1, 10, or 12.

55. (Amended) The method of claim 54, wherein the one or more additional nucleic acids promote the expression of a nucleic acid encoding a polypeptide **[an operably linked transgene]**.

58. (Amended) The method of claim 54, wherein the recursive recombination produces at least one library of recombinant nucleic acids, which library comprises at least one recombinant nucleic acid that promotes the expression of a nucleic acid encoding a polypeptide **[an operably linked transgene]**.

59. (Amended) The method of claim 53, further **[additionally]** comprising assaying the modified or recombinant nucleic acid produced by the method for the ability to promote the expression of a nucleic acid encoding a polypeptide **[an operably linked transgene]**.

61. (Amended) A nucleic acid library comprising two or more nucleic acids of claim **[claims]** 1, 10, or 12.

62. (Amended) A vector comprising at least one nucleic acid of claim **[claims]** 1, 10, 12 or 44.

65. (Amended) A cell comprising the nucleic acid of claim **[claims]** 1, 10, or 12 or the vector of claim 62.

67. (Amended) A population of cells comprising the library of claim **[claims]** 60 or 61.

68. (Amended) A composition comprising the nucleic acid of claim **[claims]** 1, 10, or 12 or the vector of claim 62 and a carrier.

70. (Amended) The composition of claim 68 **[48]**, wherein the nucleic acid or vector is present in the composition in an amount sufficient to introduce the nucleic acid or vector into cells of a subject, when the composition is administered to the subject.

71. (Amended) A composition comprising the nucleic acid of claim **[claims]** 1, 10, or 12 or the vector of claim 62 in an amount sufficient to introduce the nucleic acid or vector into cells of a subject, when the composition is administered to the subject.

72. (Amended) The composition of claim **[claims]** 70 or 71, wherein the amount is sufficient to introduce the nucleic acid or vector into cells of a subject, when the composition is administered to the subject by a route selected from the group consisting of topical administration, injection, implantation, oral administration, buccal, vaginal administration, rectal administration, and inhalation.

73. (Previously Amended Once and Herein Amended) The composition of claim **[claims]** 70 or 71, wherein the composition is administered to the subject by a route selected from the group consisting of intradermal, subdermal, subcutaneous, intramuscular, intravenous, intraperitoneal, and intrathecal.

74. (Amended) A method of producing a polypeptide, the method comprising:

(a) providing a population of cells comprising a nucleic acid of claim **[claims]** 1, 10, or 12 operably linked to a nucleic acid **[transgene]** encoding a polypeptide; and

(b) expressing the polypeptide in at least the subset of the population of cells or progeny thereof.

75. (Amended) The method of claim 74, wherein the population of cells is provided by introducing the nucleic acid operably linked to the polypeptide-encoding nucleic acid **[transgene]** into the population of cells.

91. (Amended) A nucleic acid of claim **[claims]** 1, 10, or 12 for use in producing an immunogenic effect, a prophylactic effect, or a therapeutic effect in a subject.

93. (Amended) A kit comprising a nucleic acid of claim **[claims]** 1, 10, 12, or 44.

94. (Amended) A kit comprising a vector of claim **[claims]** 62 or 63.

96. (Amended) A database comprising one or more character strings corresponding to a unique subsequence of a polynucleotide sequence selected from SEQ ID NO:1 to

SEQ ID NO:18 or a unique **[uniques]** subsequence of a complementary polynucleotide sequence thereof.

97. (Amended) The database of claim **[claims]** 95 or 96, wherein the one or more character strings is recorded in a computer-readable medium.

Please cancel claims 99 and 100 without prejudice to subsequent renewal.

101. (Amended) The method of claim **[claims]** 98 or **[99]**, comprising performing one or more operations selected from among: a local sequence comparison, a sequence alignment, a sequence identity or similarity search, a sequence identity or similarity determination, a nucleic acid motif determination, a hypothetical translation, a determination of a restriction map, a sequence recombination, or a BLAST determination.

Please add new claims 104-107 as follows:

104. (New) The nucleic acid of claim 1, wherein the polynucleotide sequence promotes expression of the polypeptide-encoding nucleic acid.

105. (New) The nucleic acid of claim 10, wherein the subsequence promotes expression of a nucleic acid encoding a polypeptide at a level about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

106. (New) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least about 98% sequence identity to a nucleotide sequence as given in any of SEQ ID NOS:1-18 but lacks the nucleotide residues corresponding to the first exon, or a complementary polynucleotide sequence thereof.

107. (New) The nucleic acid of claim 1, wherein the polynucleotide sequence or complementary polynucleotide sequence thereof promotes expression of the polynucleotide-encoding nucleic acid sufficient to induce an immune response.

Please type a plus sign (+) inside thi → [+]

(Modified) PTO/SB/21 (6-98)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/886,942
Filing Date	June 21, 2001
First Named Inventor	Juha Punnonen, *et al.*
Group Art Unit	1632
Examiner Name	Chen, Liping
Total Number of Pages in This Submission	
Attorney Docket Number	0179.210 US

ENCLOSURES ***(check all that apply)***

- [X] Fee Transmittal Form
  - [ ] Fee Attached
- [X] Amendment / Response
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [X] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- [ ] Petition to Convert to a Provisional Application
- [X] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Small Entity Statement
- [ ] Request for Refund
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Additional Enclosure(s) *(please identify below)*:

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Remarks

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Firm or Individual name	Margaret A. Powers, Reg. No. 39,804
Signature	
Dat	September 3, 2002

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Typed or printed name	Julie K. Mausen		
Signature		Date	September 3, 2002

(Modified) PTO/SB/17 (12-98)
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FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.
Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12.

TOTAL AMOUNT OF PAYMENT ($)

Complete if Known	
Application Number	09/886,942
Filing Date	June 21, 2001
First Named Inventor	Juha Punnonen, *et al*
Examiner Name	Chen, Liping
Group / Art Unit	1632
Attorney Docket No.	0179.210US

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 50-0990
Deposit Account Name: Maxygen, Inc.

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

2. [ ] **Payment Enclosed:** [ ] Check [ ] Money Order [ ] Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES

			Extra Claims		Fee from below	Fee Paid
Total Claims	183	-20** =	0	X	0	0
Independent Claims	6	-3** =	0	X	0	0
Multiple Dependent						0

***or number previously paid, if greater; For Reissues, see below*

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	78	209	39	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	110.00
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1440	218	720	Extension for reply within fourth month	
128	1960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1280	241	640	Petition to revive - unintentional	
142	1280	242	640	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	690	246	345	Filing a submission after final rejection (37 CFR 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR 1.129(b))	
				Other fee (specify) _____	
				Other fee (specify) _____	

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 110.00

SUBMITTED BY

				Complete (if applicable)	
Typed or Printed Name	Margaret A. Powers			Reg. Number	39,804
Signature	Margaret A. Powers	Date	9/03/02	Deposit Account User ID	

CERTIFICATE OF MAILING

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Typed or Printed Name	Julie K. Mausen		
Signature	Julie K. Mausen	Date	September 3, 2002

APPENDIX B

CLAIMS PENDING IN USSN 09/886,942 WITH ENTRY OF THIS AMENDMENT

1. (Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least about 98% sequence identity to at least one polynucleotide sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18, or a complementary polynucleotide sequence thereof.

2. (Amended) The nucleic acid of claim 1, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked at a level that is about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

3. (Amended) The nucleic acid of claim 2, wherein the human CMV promoter polynucleotide sequence is a Towne or AD169 human CMV promoter polynucleotide sequence.

4. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence selected from the group consisting of SEQ ID NO:1 to SEQ ID NO:18 or a complementary polynucleotide sequence thereof.

Claims 5 and 6 have been cancelled without prejudice to subsequent renewal.

7. (Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that has at least about 99% sequence identity to at least one polynucleotide sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18 or a complementary polynucleotide sequence thereof.

8. (Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that has at least about 99% sequence identity to at least one polynucleotide sequence from the group consisting of SEQ ID NO:1 to SEQ ID NO:18, or a complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of the polypeptide-encoding nucleic acid at a level that is about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

Claim 9 has been cancelled without prejudice to subsequent renewal.

10. (Amended) An isolated or recombinant nucleic acid comprising a subsequence of at least one polynucleotide sequence selected from the group consisting of SEQ ID

NO:1 to SEQ ID NO:18, said subsequence comprising nucleic acid residues at positions corresponding to position 1 to about position 909 of the consensus sequence shown in Figure 8, or a complementary polynucleotide sequence thereof.

11. (Amended) The nucleic acid of claim 10, wherein the subsequence promotes the expression of a nucleic acid encoding a polypeptide to which the subsequence is operably linked.

12. (Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that hybridizes under highly stringent conditions over substantially the entire length of a the polynucleotide sequence of claim 1.

13. The nucleic acid of claim 12, wherein the highly stringent conditions are selected such that a polynucleotide sequence selected from SEQ ID NO:1 to SEQ ID NO:18 hybridizes to its perfect complement with at least a 5-fold higher signal to noise ratio than for hybridization of the perfect complement to a control nucleic acid comprising a human CMV promoter polynucleotide sequence.

14. (Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that promotes the expression of the polypeptide-encoding nucleic acid at a level that differs from the expression level of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a nucleic acid sequence corresponding to a human CMV promoter polynucleotide sequence.

15. (Amended) The nucleic acid of claim 14, wherein the polypeptide-encoding nucleic acid encodes luciferase, and the expression level is determined in an *in vitro* luciferase assay.

16. (Amended) The nucleic acid of claim 14, wherein the polypeptide-encoding nucleic acid encodes β-galactosidase, the polypeptide-encoding nucleic acid is expressed *in vivo*, and the expression level is determined by measuring the serum titer of anti-β-galactosidase antibodies.

17. (Amended) The nucleic acid of claim 14, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid at a level that is higher than the highest expression level of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

18. (Amended) The nucleic acid of claim 17, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid at a level that is 2-fold higher than the highest expression level of the polypeptide-encoding nucleic acid when the

polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

19. (Amended) The nucleic acid of claim 14, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid at a level that is lower than the lowest expression level of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

20. (Amended) The nucleic acid of claim 19, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid at a level that is 2-fold lower than the lowest expression level of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

21. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues in a region corresponding to about nucleotide residue positions 830-835 or 841-844 of the consensus sequence shown in Figure 8.

22. (Amended) The nucleic acid of claim 21, wherein the nucleic acid comprises a deletion of nucleotide residues at positions corresponding to about nucleotide residue positions 830-835 or 841-844 of the consensus sequence.

23. (Amended) The nucleic acid of claim 22, wherein the nucleic acid comprises a deletion of the nucleotide residues at positions corresponding to about nucleotide residue positions 830-835 and 841-844 of the consensus sequence.

24. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises nucleotide residues of a Rhesus monkey CMV promoter polynucleotide sequence at positions corresponding to about nucleotide residue positions 817-863 of the consensus sequence shown in Figure 8.

25. (Previously Amended Once) The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence selected from GACGCCGGAGG (SEQ ID NO:38) and GACGTCGGAG (SEQ ID NO:39).

26. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises an insertion of a nucleotide residue, as compared to the human Towne CMV promoter sequence, after the nucleotide residue corresponding to that positioned at position 853 of the consensus sequence shown in Figure 8.

27. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues in a region corresponding to about nucleic acid residue positions 684-735 of the consensus sequence shown in Figure 8.

28. (Amended) The nucleic acid of claim 27, wherein the nucleic acid comprises a deletion of nucleotide residues corresponding to about nucleotide residue positions 684-735 of the consensus sequence.

29. (Previously Amended Once) The nucleic acid of claim 1, wherein the nucleic acid comprises the polynucleotide sequence AATGGGCGGTC (SEQ ID NO:40).

30. (Amended) The nucleic acid of claim 1, wherein the nucleic acid does not comprise nucleic acid residues beyond about the nucleotide residue position corresponding to position 909 of the consensus sequence, numbered according to the consensus sequence shown in Figure 8.

31. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence comprising nucleic acid residues at positions corresponding to about position 1 to about position 930 of the consensus sequence shown in Figure 8.

32. (Amended) The nucleic acid of claim 31, wherein the nucleic acid does not comprise nucleic acid residues beyond about the nucleotide residue at the position corresponding to position 930 of the consensus sequence shown in Figure 8.

33. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence comprising nucleic acid residues at nucleic acid residue positions corresponding to positions 1 to 932 of the consensus sequence shown in Figure 8.

34. (Amended) The nucleic acid of claim 33, wherein the nucleic acid does not comprise nucleotide residues beyond the nucleotide residue corresponding to position 932 of the consensus sequence shown in Figure 8.

35. (Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues in a region corresponding to about nucleotide residue positions 319-512 of the consensus sequence shown in Figure 8.

36. (Amended) The nucleic acid of claim 35, wherein the nucleic acid comprises a deletion of nucleotide residues corresponding to about nucleotide residue positions 319-512 of the consensus sequence.

37. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:21 or a complementary polynucleotide sequence thereof.

38. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:8 (6A8) or a complementary polynucleotide sequence thereof.

39. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:11 (6F6) or a complementary polynucleotide sequence thereof.

40. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:6 (3C9) or a complementary polynucleotide sequence thereof.

41. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:9 (6B2) or a complementary polynucleotide sequence thereof.

42. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:2 (11E2) or a complementary polynucleotide sequence thereof.

43. The nucleic acid of claim 1, wherein the polynucleotide sequence comprises SEQ ID NO:3 (12C9) or a complementary polynucleotide sequence thereof.

44. (Amended) The nucleic acid of claim 1, 10 or 12, wherein the polynucleotide sequence is operably linked to a nucleic acid encoding a polypeptide to form an expression cassette.

45. (Amended) The nucleic acid of claim 44, wherein the polypeptide-encoding nucleic acid encodes a viral polypeptide.

46. (Amended) The nucleic acid of claim 44, wherein the polypeptide-encoding nucleic acid encodes a polypeptide selected from the group consisting of an immunogen, an immunomodulatory molecule, an antigen, an adjuvant, an allergen, an antibody, a bacterial toxin, a cytokine, a cytokine receptor, and a co-stimulatory molecule.

47. (Amended) The nucleic acid of claim 46, wherein the polypeptide-encoding nucleic acid encodes an antigen selected from the group consisting of a cancer antigen, a hepatitis B surface antigen, a hepatitis A antigen, and a hepatitis C antigen.

48. (Amended) The nucleic acid of claim 46, wherein the polypeptide-encoding nucleic acid encodes a co-stimulatory polypeptide that binds to a CD28 or CTLA-4 receptor.

49. (Amended) A composition produced by the cleaving of one or more nucleic acids of claim 1, 10, or 12, wherein the cleaving comprises mechanical, chemical, or enzymatic cleavage.

50. The composition of claim 49, wherein the cleaving comprises enzymatic cleavage with a restriction endonuclease, an RNAse or a DNAse.

51. (Amended) A composition produced by a process comprising incubating one or more nucleic acids of claim 1, 10, or 12 in the presence of deoxyribonucleotide triphosphates and a nucleic acid polymerase.

52. The composition of claim 51, wherein the nucleic acid polymerase is a thermostable polymerase.

53. (Amended) A method of producing a modified or recombinant nucleic acid comprising mutating or recombining a nucleic acid of claim 1, 10, or 12.

54. The method of claim 53, comprising recursively recombining the nucleic acid with one or more additional nucleic acids.

55. (Amended) The method of claim 54, wherein the one or more additional nucleic acids promote the expression of a nucleic acid encoding a polypeptide.

56. The method of claim 54, wherein the recursive recombination is performed *in vitro*.

57. The method of claim 54, wherein the recursive recombination is performed *in vivo*.

58. (Amended) The method of claim 54, wherein the recursive recombination produces at least one library of recombinant nucleic acids, which library comprises at least one recombinant nucleic acid that promotes the expression of a nucleic acid encoding a polypeptide.

59. (Amended) The method of claim 53, further comprising assaying the modified or recombinant nucleic acid produced by the method for the ability to promote the expression of a nucleic acid encoding a polypeptide.

60. A nucleic acid library produced by the method of claim 53.

61. (Amended) A nucleic acid library comprising two or more nucleic acids of claim 1, 10, or 12.

62. (Amended) A vector comprising at least one nucleic acid of claim 1, 10, 12 or 44.

63. The vector of claim 62, wherein the vector is an expression vector.

64. The vector of claim 62, wherein the vector is selected from a plasmid, a cosmid, a phage, a virus or fragment thereof, a bacterial artificial chromosome (BAC), a yeast artificial chromosome (YAC).

65. (Amended) A cell comprising the nucleic acid of claim 1, 10, or 12 or the vector of claim 62.

66. The cell of claim 65, wherein the cell comprises a human cell.

67. (Amended) A population of cells comprising the library of claim 60 or 61.

68. (Amended) A composition comprising the nucleic acid of claim 1, 10, or 12 or the vector of claim 62 and a carrier.

69. The composition of claim 68, wherein the excipient is a pharmaceutically acceptable carrier.

70. (Amended) The composition of claim 68, wherein the nucleic acid or vector is present in the composition in an amount sufficient to introduce the nucleic acid or vector into cells of a subject, when the composition is administered to the subject.

71. (Amended) A composition comprising the nucleic acid of claim 1, 10, or 12 or the vector of claim 62 in an amount sufficient to introduce the nucleic acid or vector into cells of a subject, when the composition is administered to the subject.

72. (Amended) The composition of claim 70 or 71, wherein the amount is sufficient to introduce the nucleic acid or vector into cells of a subject, when the composition is administered to the subject by a route selected from the group consisting of topical administration, injection, implantation, oral administration, buccal, vaginal administration, rectal administration, and inhalation.

73. (Previously Amended Once and Herein Amended) The composition of claim 70 or 71, wherein the composition is administered to the subject by a route selected from the group consisting of intradermal, subdermal, subcutaneous, intramuscular, intravenous, intraperitoneal, and intrathecal.

74. (Amended) A method of producing a polypeptide, the method comprising:

(a) providing a population of cells comprising a nucleic acid of claim 1, 10, or 12 operably linked to a nucleic acid encoding a polypeptide; and

(b) expressing the polypeptide in at least the subset of the population of cells or progeny thereof.

75. (Amended) The method of claim 74, wherein the population of cells is provided by introducing the nucleic acid operably linked to the polypeptide-encoding nucleic acid into the population of cells.

76. The method of claim 74, further comprising isolating the polypeptide from the cells.

77. The method of claim 74, wherein the cells are in culture.

78. The method of claim 77, comprising expressing the polypeptide by culturing the population or subset of the population of cells or progeny thereof in a nutrient medium under conditions in which the nucleic acid promotes expression of the polypeptide.

79. The method of claim 78, further comprising isolating or recovering the polypeptide from the cells or from the nutrient medium.

80. The method of claim 74, wherein the cells comprise mammalian cells selected from fertilized oocytes, embryonic stem cells, or pluripotent stem cells, the method further comprising generating a transgenic mammal expressing the polypeptide.

81. The method of claim 80, further comprising recovering the polypeptide from the transgenic mammal or a byproduct of the transgenic mammal.

82. The method of claim 74, wherein the cells are *in vivo* in a subject.

83. The method of claim 82, wherein the nucleic acid is introduced into cells in culture, and the cells are subsequently introduced into the subject.

84. The method of claim 82, wherein the nucleic acid is introduced into the cells of the subject by administering the nucleic acid directly to the subject.

85. The method of claim 84, wherein the nucleic acid is administered to the subject by a route selected from the group consisting of topical administration, injection, implantation, oral administration, vaginal administration, rectal administration, and inhalation.

86. The method of claim 85, wherein the nucleic acid is administered to the subject by a route selected from the group consisting of intradermal, subdermal, subcutaneous, intramuscular, intravenous, intraperitoneal, and intrathecal.

87. The method of claim 84, wherein the nucleic acid is administered to the subject by topical administration, injection, or using a gene gun.

88. The method of claim 82, wherein the subject is a human.

89. The method of claim 82, wherein the polypeptide is expressed in an amount sufficient to produce a desired effect in the subject.

90. The method of claim 89, wherein the desired effect comprises an immunogenic effect, a prophylactic effect, or a therapeutic effect.

91. (Amended) A nucleic acid of claim 1, 10, or 12 for use in producing an immunogenic effect, a prophylactic effect, or a therapeutic effect in a subject.

92. The nucleic acid of claim 91, wherein the subject is a human.

93. (Amended) A kit comprising a nucleic acid of claim 1, 10, 12, or 44.

94. (Amended) A kit comprising a vector of claim 62 or 63.

95. A database comprising one or more character strings corresponding to a polynucleotide sequence selected from SEQ ID NO:1 to SEQ ID NO:18 or a complementary polynucleotide sequence thereof.

96. (Amended) A database comprising one or more character strings corresponding to a unique subsequence of a polynucleotide sequence selected from SEQ ID NO:1 to SEQ ID NO:18 or a unique subsequence of a complementary polynucleotide sequence thereof.

97. (Amended) The database of claim 95 or 96, wherein the one or more character strings is recorded in a computer-readable medium.

98. A method for manipulating a sequence record in a computer system, the method comprising:

(a) reading a character string corresponding to a polynucleotide sequence selected from SEQ ID NO:1 to SEQ ID NO:18, or a complementary polynucleotide sequence thereof;

(b) performing an operation on the character string; and

(c) returning a result of the operation.

Claims 99 and 100 have been cancelled without prejudice to subsequent renewal.

101. (Amended) The method of claim 98, comprising performing one or more operations selected from among: a local sequence comparison, a sequence alignment, a sequence identity or similarity search, a sequence identity or similarity determination, a nucleic acid motif determination, a hypothetical translation, a determination of a restriction map, a sequence recombination, or a BLAST determination.

102. The method of claim 101, comprising aligning the selected character string with one or more additional character strings corresponding to a polynucleotide sequence.

103. The method of claim 101, wherein the operation comprises transmitting the character string to a device capable of producing a nucleic acid comprising the polynucleotide sequence corresponding to the character string.

Please add new claims 104-107 as follows:

104. (New) The nucleic acid of claim 1, wherein the polynucleotide sequence promotes expression of the polypeptide-encoding nucleic acid.

105. (New) The nucleic acid of claim 10, wherein the subsequence promotes expression of a nucleic acid encoding a polypeptide at a level about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence.

106. (New) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least about 98% sequence identity to a nucleotide sequence as given in any of SEQ ID NOS:1-18 but lacks the nucleotide residues corresponding to the first exon, or a complementary polynucleotide sequence thereof.

107. (New) The nucleic acid of claim 1, wherein the polynucleotide sequence or complementary polynucleotide sequence thereof promotes expression of the polynucleotide-encoding nucleic acid sufficient to induce an immune response.